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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/402,450	09/01/1989	GEORGE J. MURAKAWA		8131

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EXAMINER	
MARSCHEL, ARDIN H	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	07/402,450	MURAKAWA ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34,35,38,39,42-44 and 50-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,35,38,39,42-44, & 50-113* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date (2 sheets)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final, filed on 6/4/04, has been entered.

The adverse decision, mailed 4/5/04, from Interference Number 105,055 regarding the instant application is noted.

Applicants' arguments, filed 6/4/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 34, 35, 38, 39, 42-44, and 50-113 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the disclosure as filed regarding reference viral RNA sequence reveals that for such viral reference practice only insertion of HIV-1 3'-ORF (nef) sequence to result in a larger reference viral RNA sequence for usage in amplification mixtures is set forth in the entire original specification as filed on page 6, lines 15-29.

No other viral RNA insertion for reference preparation has been disclosed as originally filed. Therefore the above listed instant claims contain NEW MATTER due to containing limitations to non-target RNA viral sequences which are "generic" which are thus not disclosed as filed. This issue applies, for example, to reference types (i), (ii), and (iv) and corresponding types in other instant claims.

The separate and sequential probe removal and hybridization as set forth in the methods of instant claims 50 and 53, and those dependent therefrom, have not been found as disclosed as filed and therefore also are NEW MATTER limitations. Consideration of the support in REMARKS, filed 6/4/04, such as in original claim 27 etc. has failed to provide written basis for such separate and sequential probe methodology.

PRIOR ART REJECTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34, 35, 38, 39, 44, 56, 59-63, 66, 67, 70, 71, 74-77, 80, 83, 86-89, 92, 95, 98, 99, 102, 104, 105-108, and 111 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Chelly et al. [Nature 333:858 (1988); already of record]; taken in view of Mullis et al. (P/N 4,683,195).

In Remarks, filed 6/4/04, applicants argue that the instant claims should receive priority to parent application, serial number 07/148,959, filed 1/27/88. Consideration of the entirety of the disclosure of said 07/148,959 reveals that a control plasmid reference sequence is utilized therein but made different from the target sequence only via an insert. Therefore the reference nucleic acid therein contains an amplified section which is larger than the target experimental nucleic acid. This larger reference size is then detectable after amplification. No disclosure other than insertion of nucleic acid to result in a reference has been found is said parent application. Also, no usage of a heterologous reference sequence wherein the experimental target and the reference nucleic acid are amplified each by their own respective primer sets has been found. Thus, regarding these types of embodiments, neither priority nor benefit is granted to said parent. Therefore, the priority date for the instant claimed subject matter as rejected herein based on Chelly et al. is the instant application filing date of 9/1/89. Therefore, the publication date of Chelly et al. is more than one year prior to the date of the subject matter as rejected hereinunder.

Chelly et al. describes the simultaneous application protein expression detection via a dystrophin RNA transcript with aldolase A RNA transcript starting material via reverse transcription in a DNA amplification PCR procedure described on pages 858-860 with results shown in Figures 2 and 3 as well as quantitative amounts in Table 1 on page 859. The reference aldolase A transcript size is 181 basepairs which is smaller

than the dystrophin RNA transcript target which is amplified, which is 201 basepairs. This is shown distinctly in Figure 3, part a, and with related discussion. As noted above, this type of amplified segment size relationship is given priority regarding only the filing date of the instant application and is thus predated by this description in Chelly et al. It is noted that reference types (i) and (iii) cited in instant claim 34 are thus described by the Chelly et al. reference disclosure. The instant kit claims are also described because the kits as instantly claimed include embodiments which are only the reaction mixtures as set forth in the reference.

Mullis et al. suggests and motivates the source of sequence for targets for PCR type amplification to include any source; RNA or DNA; cloned, natural, viral, higher organisms, etc. in the section in column 7, line 66, through column 8, line 8.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to apply the amplification techniques for quantitation as are set forth above in Chelly et al. to any source of nucleic acid, RNA or DNA, including viral sources as motivated and suggested by Mullis et al. thus resulting in the practice of the instant invention to produce the improvements of quantitation in PCR applications as in Chelly et al.

Claims 34, 35, 38, 39, 42-44, 56, 57, 59-63, 66, 67, 70, 71, 72, 74-77, 80, 83, 84, 86-89, 92, 95, 96, 98, 99, 102, 104, 105-108, and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chelly et al. [Nature 333:858 (1988); already of record]; taken in view of Mullis et al. (P/N 4,683,195); taken further in view of Sninsky et al. (P/N 5,176,995).

This rejection is directed to the specific viral embodiments within the instant claims, in particular the HIV sequence embodiments.

The above combination of Chelly et al. taken with Mullis et al. has been described above as suggesting viral amplification practice, but lacks specific viral descriptions therein. It is noted that HIV viruses are well known in the art as a type of interesting virus.

In the title and abstract, Sninsky et al. describes viral detection via amplification with primers etc. as in PCR as summarized also in Chelly et al. and Mullis et al. In Sninsky et al. in column 4, line 34, through column 11, line 12, AIDS or HIV viral amplification is described of the PCR type. This suggests and motivates PCR techniques as being performable with a reasonable expectation of success.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform amplification techniques, especially including HIV sequences, utilizing amplification techniques in the art such as described in the combination of Chelly et al. with Mullis et al. which results in the practice of the HIV embodiments of the instant invention with a reasonable expectation of success given the descriptions in Sninsky et al.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 25, 2005

Ardin H. Marschel 6/26/05

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER